51. The method according to claim 32 wherein said human parathyroid hormone is selected from PTH(1-31), PTH(1-34), PTH(1-37), PTH(1-38), PTH(1-41) and PTH(1-84).

52. The method according to claim 32 wherein said parathyroid hormone is human PTH(1-34).

53. The method according to claim 39 wherein said parathyroid hormone is human PTH(1-84).

54. The method according to claim 32 wherein said parathyroid hormone is administered for at least about 12 months up to 3 years.

55. The method according to claim 32 wherein said daily dose is 20 ug.

Remarks

Applicant has amended the claims to more clearly point out that which is considered to be the present invention, by replacing pending claims 1-16 with new claims 17-55. Applicant respectfully requests examination of this application as soon as possible.

Respectfully submitted,

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9. A method for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis, said method comprising

administering to said subject a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months up to 3 years.

10. The method of claim 9 wherein said human subject is at risk of or has osteoporosis arising from an age-related hypogonadal condition.

11. The method of claim 10 wherein said subject human is a postmenopausal woman.

12. The method of claim 9 wherein said daily dose is 20 μg.

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13. The method of claim 9 wherein said daily dose is administered for at least about 24 months.

14. An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, said composition comprising a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid and

said packaging material comprising printed matter which indicates that

said composition is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months up to 3 years.

15. Use of a parathyroid hormone consisting of amino acid sequence 1-34 of human parathyroid hormone for the manufacture of a medicament for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis,

wherein said medicament is administered to said subject without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months up to 3 years.

16. Use according to claim 15 wherein said medicament is contained within a packaging material,

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said packaging material comprising printed matter which indicates that

said medicament is effective for concurrently reducing the risk of both vertebral and non-vertebral bone fracture in a human subject at risk of or having osteoporosis when administered to said subject such that said parathyroid hormone is administered

without concurrent administration of an antiresorptive agent other than vitamin D or calcium,

in a daily dose of 20 μg or 40 μg for at least about 12 months up to 3 years.

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Remarks

Applicant has amended the specification to correct three instances of a clerical error whereby daily fixed dosages for human subjects, which are correctly set forth as 20 or 40 "μg/day" in multiple instances in Example 3 (see, for instance, "Dosage and Administration" at page 46), were incorrectly transcribed as body mass-dependent dosages, namely "μg/kg/day". Body mass-dependent dosages are consistently used throughout the specification in reference to non-human subjects.

Applicant has amended the claims to more clearly point out that which is considered to be the present invention, by replacing amended pending claims 1-8, filed in the corresponding PCT application (with handwritten amendments) during an in person interview on 20 July 2000, which are the subject of the International Patent Examination Report in that PCT case. For clarity, claims 1-8, including the hand-written amendments, have been retyped as amended claims 9-16 filed herewith. Applicant respectfully requests examination of this application as soon as possible.

Respectfully submitted,

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